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| APPLICATION NO.           | FILN            | NG DATE | FIRST NAMED INVENTOR        | ATTORNEY DOCKET NO. | CONFIRMATION NO |
|---------------------------|-----------------|---------|-----------------------------|---------------------|-----------------|
| 10/760,969                | 01/20/2004      |         | Fanny Delia Marchosky Kogan | 1490                |                 |
| 7:                        | 7590 02/10/2005 |         |                             | EXAMINER            |                 |
| Eugenio J. To             | rres            |         |                             | MCCORMICK EWO       | LDT, SUSAN BETH |
| Suite 1<br>1060 Ashford A | ۷ve.            |         |                             | ART UNIT            | PAPER NUMBER    |
| San Juan, PR 00907        |                 |         | 1654                        |                     |                 |

DATE MAILED: 02/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|  | Application No.   | Applicant(s)   |  |  |  |  |  |
|--|---|--|--|--|--|--|--|
| Office Action Summary  | 10/760,969  | MARCHOSKY KOGAN, FANNY<br>DELIA  |  |  |  |  |  |
| Office Action Summary  | Examiner  | Art Unit   |  |  |  |  |  |
|  | Susan B. McCormick-Ewoldt   | 1654   |  |  |  |  |  |
| The MAILING DATE of this communication app Period for Reply  | ears on the cover sheet with the c  | orrespondence address  |  |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.13 after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply If NO period for reply is specified above, the maximum statutory period we Failure to reply within the set or extended period for reply will, by statute, Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | 66(a). In no event, however, may a reply be time within the statutory minimum of thirty (30) days fill apply and will expire SIX (6) MONTHS from cause the application to become ABANDONE                         | nely filed s will be considered timely. the mailing date of this communication. O (35 U.S.C. § 133). |  |  |  |  |  |
| Status   |   |  |  |  |  |  |  |
| 1)⊠ Responsive to communication(s) filed on 20 Ja  | nuary 2004.   |  |  |  |  |  |  |
|  | action is non-final.  |  |  |  |  |  |  |
| <u></u>  |   | secution as to the merits is   |  |  |  |  |  |
|  | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. |  |  |  |  |  |  |
| Disposition of Claims  |   |  |  |  |  |  |  |
| 4)⊠ Claim(s) <u>1-6</u> is/are pending in the application.   |   |  |  |  |  |  |  |
|  | 4a) Of the above claim(s) is/are withdrawn from consideration.  |  |  |  |  |  |  |
| 5) Claim(s) is/are allowed.  | _   |  |  |  |  |  |  |
| 6) Claim(s) is/are rejected.   |   |  |  |  |  |  |  |
| 7) Claim(s) is/are objected to.  | _   |  |  |  |  |  |  |
| 8) Claim(s) 1-6 are subject to restriction and/or ele  | ection requirement.   | •  |  |  |  |  |  |
| Application Papers   |   |  |  |  |  |  |  |
| 9)☐ The specification is objected to by the Examiner   | r.  |  |  |  |  |  |  |
| 10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.   |   |  |  |  |  |  |  |
| Applicant may not request that any objection to the o  |   |  |  |  |  |  |  |
| Replacement drawing sheet(s) including the correcti  | ÷ , ,   | ` '  |  |  |  |  |  |
| 11) The oath or declaration is objected to by the Ex   |   | • •  |  |  |  |  |  |
| Priority under 35 U.S.C. § 119   | ·   | wings research see a re-   |  |  |  |  |  |
| 12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of:   | priority under 35 U.S.C. § 119(a)   | -(d) or (f).   |  |  |  |  |  |
| 1. Certified copies of the priority documents  |   |  |  |  |  |  |  |
| 2. Certified copies of the priority documents  | s have been received in Application   | on No  |  |  |  |  |  |
| 3. Copies of the certified copies of the prior   | ity documents have been receive   | d in this National Stage   |  |  |  |  |  |
| application from the International Bureau  | (PCT Rule 17.2(a)).   |  |  |  |  |  |  |
| * See the attached detailed Office action for a list of  |   | d.   |  |  |  |  |  |
|  |   |  |  |  |  |  |  |
| Attachment(s)  |   |  |  |  |  |  |  |
| 1) Notice of References Cited (PTO-892)  4) Interview Summary (PTO-413)  |   |  |  |  |  |  |  |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)   | Paper No(s)/Mail Da 5) Notice of Informal Pa  | ite<br>atent Application (PTO-152)   |  |  |  |  |  |
| Paper No(s)/Mail Date 6) Other:  |   |  |  |  |  |  |  |

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## **DETAILED ACTION**

## Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-2, drawn to a composition for optimization of the immune system, classified in class 424, subclass 754, for example.
- II. Claim 3, drawn to a method of preparing the composition, classified in class 754, subclass 754, for example.
- III. Claims 4-6, drawn to a method of administering the composition, classified in class 424, subclass 754, for example.

Inventions I and II are related as a product and process of making. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product may be extracted by a different process such as using a methanol or ethanol extraction processes.

Inventions I and III are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP \$806.05(h)). In the instant case there are numerous methods of reducing infections in the immune system (including numerous prescription drugs) that do not require the product of Group III.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions invention II is a method of preparing the composition and invention III is a method of administering the composition.

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Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

The Examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the Examiner before the patent issues. See MPEP § 804.01.

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## Future Correspondence

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Susan B. McCormick-Ewoldt whose telephone number is (571) 272-0981. The Examiner can normally be reached Monday through Thursday from 6:00 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Bruce Campell, can be reached on (571) 272-0974. The official fax number for the group is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free)

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